



BRIAN SANDOVAL
Governor

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID
NOTICE OF OPEN PUBLIC MEETING

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

NEVADA MEDICAID
PHARMACY & THERAPEUTICS COMMITTEE

Las Vegas Chamber of Commerce
6671 Las Vegas Blvd. S., Suite 300
Las Vegas, NV 89119

Magellan Medicaid Administration
885 Trademark Dr., Suite 150
Reno, NV 89521

Committee Approved
Meeting Minutes
December 16, 2010

Committee Members Present

Las Vegas: Rudy Manthei, MD; Joseph Adashek, MD; Weldon Havins, MD; Constance Kalinowski, MD; Shamim Nagy, MD

Reno: Judy Britt, Pharm.D.; Michael Hautekeet, R.Ph.; Justin Holt, Pharm.D

Absent: David Chan, R.Ph.; Chad Luebke, Pharm.D.

Others Present

DHCFP:

Las Vegas: Gabriel Lithier, Deputy Attorney General

Reno: Coleen Lawrence, Chief, Program Services

Magellan Medicaid Administration

Las Vegas: Paula Townsend, Pharm.D., Clinical Account Manager; Shirley Hunting

Reno: Dave Wuest, R.Ph., Clinical Account Manager; Judy LaFleur

Others

Las Vegas: Doug Powell-Forest; Jola Turner-Rosenthal-Forest; Irene Camerino-Forest; Eric Byrnes-Alcon; Chase Freeman-Pfizer; Cindy Hansen-Pfizer, Michazel Pinocei-Pfizer; Roy Palmer-Pfizer; Sandy Sierawski-Pfizer; Bret Ferguson-Pfizer; Lori Howarth-Bayer; George Yantake-Actelion; Patrick Hall-Actelion; Jane Stephen-Allergan; Ken Grant, MD-Touro University; Dan Bay-Abbott; Brooks Hubbard-Boehringer Ingelheim; Laura Federico-Lilly; John Brokers-Lilly; Tori Magee-Dyax; Christine Par-FMA; Deborah Wafer-Filead; Lise Collins-Fibro Support Group

Reno: Steve Nelson-Merck; Jeff Scheneman-Pfizer; Jessica Ferrato-GCG of Nevada; Chelsea Capurro-GCG of Nevada

Copies of written testimony submitted by the public were distributed to the Committee.

I. Call to Order and Roll Call

Chairman Rudy Manthei called the meeting to order at 1:00 p.m.

II. Review and Approval of the September 23, 2010 Meeting Minutes

MOTION: Joseph Adashek motioned to approve the minutes as presented.

SECOND: Shamim Nagy

VOTES: Unanimous

MOTION CARRIED

III. New Drug Class Reviews

Item E. Fibromyalgia Agents was taken out of order and reviewed as the first item of business under agenda item III.

A. Oral Agents for Gout: Xanthine Oxidase Inhibitors

Public Comment

No comment.

Drug Class Review Presentation – Magellan Medicaid Administration

Dr. Townsend stated that the Xanthine Oxidase Inhibitors are a proposed new PDL class. There are two products, allopurinol, previously marketed as the brand Zyloprim® and febuxostat currently marketed as Uloric®. Allopurinol is indicated for primary or secondary gout, management of elevated serum uric acid due to leukemia/lymphoma or other malignancies treated with chemotherapy, and recurrent calcium oxalate calculi in patients whose uric acid exceeds 750-800mg per day. Febuxostat is indicated for chronic hyperuricemia in patients with gout. Febuxostat studies included high doses and non-approved doses greater than 80mg per day. The first and second trials for the initial Phase 3 studies compared febuxostat 80mg up to 240mg per day to allopurinol 100mg to 300mg per day. Per the FDA, because of a possible cardiovascular safety signal that was identified in the analysis of the initial trials, a third study was conducted comparing febuxostat 40mg and 80mg per day to allopurinol 300mg per day or 200mg in patient's with renal dysfunction. Febuxostat 40mg was superior to allopurinol in reducing serum uric acid to levels less than 6mg/dL, but the incidence of gout flares was similar in the first trial and greater with febuxostat in the second trial. The third trial compared febuxostat 40mg and 80mg to allopurinol 40mg. The primary outcome showed the percentage of patients with less than 6mg/dL on febuxostat 40mg was 45% and for allopurinol it was 42%. Febuxostat 40mg was non-inferior to allopurinol in that trial; at 80mg, 67% of patients achieved serum uric acid levels of less than 6mg/dL. The most common adverse reactions in patients treated with febuxostat were liver function abnormalities, nausea, joint pain and rash. Both agents are dosed once daily. Overall, febuxostat appears to be an alternative to allopurinol in patients who fail to achieve serum uric acid levels less than 6mg/dL after three months or in those patients who are intolerant to allopurinol. Claims data indicates that in the past three months, there have been 385 recipients taking allopurinol and 24 taking febuxostat. It is the recommendation of DHCFP and Magellan Medicaid Administration that allopurinol and febuxostat be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Populations

MOTION: Constance Kalinowski motioned that allopurinol and febuxostat be considered therapeutic alternatives.

SECOND: Shamim Nagy

VOTES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that it is the recommendation of DHCFP and Magellan Medicaid Administration that allopurinol be the preferred agent on the PDL.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Nagy asked if there is failure with allopurinol, will febuxostat be available. Dr. Townsend stated that if there is failure of the preferred drug, the non-preferred drug is available. Coleen Lawrence added that if the recipient meets any of the seven listed criteria for approval as outlined in the Preferred Drug List Exception Criteria, a non-preferred drug will be available.

MOTION: Judy Britt motioned to accept Magellan's recommendation to add allopurinol to the PDL.
SECOND: Justin Holt
VOTES: Unanimous
MOTION CARRIED

B. Ophthalmic Antibiotics: Macrolides

Public Comment

No comment.

Drug Class Review Presentation – Magellan Medicaid Administration

Dr. Townsend stated that the ophthalmic antibiotics macrolides is a proposed new PDL class. Agents within the class are erythromycin ointment and azithromycin solution which is marketed at AzaSite®. Within the ophthalmic antibiotics, there is currently a PDL class for fluoroquinolones only; the other classes of antibiotics are all available. Erythromycin is indicated for superficial ocular infections involving the conjunctiva or cornea and for ophthalmia neonatorum due to chlamydia trachomatis and prophylaxis of ophthalmia neonatorum due to Neisseria gonorrhoeae. AzaSite® is indicated for the treatment of bacterial conjunctivitis. Many ophthalmic antibiotics are effective for the treatment of bacterial conjunctivitis as noted on pages 1 and 2 of the therapeutic class review. In the majority of children with acute conjunctivitis, the etiology is bacterial in origin and in the majority of adults, viral in origin. Erythromycin ointment is preferred by some clinicians as the ointment provides a longer contact time in the eye. AzaSite® is azithromycin in the vehicle DuraSite® which is slightly viscous and has some bioadhesive properties which potentially allows for prolongation of the drug residence time and increased bioavailability to the ocular surface. The only trial available compared AzaSite® to tobramycin and showed similar efficacy to tobramycin. Erythromycin is dosed one-half inch to the affected eye up to six times daily; AzaSite® one drop in the affected eye twice daily for two days then once daily for five days. Ophthalmic antibiotic claims data for the past three months indicates 203 Vigamox® claims; 196 polymyxin B sulfate trimethoprim claims; 194 erythromycin claims; 127 gentamicin and 105 tobramycin claims. There were 39 claims for AzaSite® for 29 recipients (9 with multiple refills); 4 of the recipients were less than 18 years old with 19 recipients over the age of 60. It is the recommendation of DHCFP and Magellan Medicaid Administration that erythromycin ophthalmic ointment and azithromycin ophthalmic solution (AzaSite®) be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Populations

MOTION: Shamim Nagy motioned that erythromycin ophthalmic ointment and azithromycin ophthalmic solution (AzaSite®) be considered therapeutic alternatives.
SECOND: Weldon Havins
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that it is the recommendation of DHCFP and Magellan Medicaid Administration that erythromycin ophthalmic ointment be the preferred agent on the PDL.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Weldon Havins motioned that erythromycin ophthalmic ointment be the preferred agent on the PDL.
SECOND: Joseph Adashek

Dr. Manthei stated that he is not aware of anyone using an ointment for treating either conjunctivitis, since there are problems with blurring of vision, or for treating blepharitis. With ophthalmologists, AzaSite® is the preferred agent for blepharitis.

Dr. Townsend stated that erythromycin ointment is primarily used in pediatrics. There is discussion in some of the review papers that some ophthalmologists prefer the ointment in young children and drops in the older children. This proposed new class is for the malacrolides. With the exception of the fluoroquinolones, which is a managed PDL class, there are many antibiotics indicated for the treatment of bacterial conjunctivitis which are not in a managed class and are openly available.

VOTES: Unanimous

MOTION CARRIED

C. Pulmonary Hypertension: Oral Agents

Public Comment

Sandy Sierawski, Pfizer, spoke in support of Revatio® (sildenafil). Revatio® clinical studies have demonstrated positive effects on symptoms, quality of life and prolonged survival of pulmonary hypertension patients. In November, 2009, the FDA approved an intravenous formulation of Revatio® making it the only FDA-approved phosphodiesterase 5 (PDE-5) inhibitor available in both tablet and intravenous formulations which is important in extending continuity of care for patients if they are unable to take oral medications. As noted in the therapeutic review document provided by Provider Synergies, efficacy of Revatio® is further exemplified in guidelines for the treatment of pulmonary hypertension. It is recommended as the first-line agent in patients with Functional Class II and III by the American College of Cardiology Foundation and the American Heart Association. The American College of Chest Physicians recommends Revatio® in pulmonary hypertension patients in Functional Class II and III at a Level A recommendation. Revatio® is well tolerated with overall discontinuation rates that are comparable to placebo from a pivotal trial. There are no adverse effects on hepatic function therefore there is no need for liver function tests. In the 2010 CMS drug utilization data for Nevada, Revatio® was 54% of the prescriptions over the last year. Revatio® has demonstrated safety and efficacy in the treatment of patients with pulmonary hypertension, is the only PDE-5 inhibitor to demonstrate a decrease in time to clinical worsening when added to epoprostenol therapy and is available in both IV and oral formulations. She requested that Revatio® be added to the PDL.

George Yasutzke, Actelion, spoke in support of Tracleer® for the treatment of pulmonary arterial hypertension (PAH). Tracleer® is the only endothelin receptor antagonist indicated for PAH patients in Functional Class II, III and IV symptoms and has been shown to significantly improve functional class and delay the time to clinical worsening. Tracleer® has been evaluated in six randomized control trials in various patient populations including idiopathic pulmonary arterial hypertension, pulmonary arterial hypertension associated with connective tissue disease, congenital heart disease and HIV. In two pivotal trials, patients had survival rates of 93% and 84% in one and two years when compared to the NIH registry which had survivals of 68% and 48% at one and two years respectively. Tracleer® is the only endothelin receptor antagonist proven to significantly delay time to clinical worsening in three separate randomized placebo-controlled trials and included a 33% reduction in hospitalization compared to placebo. The safety profile has been well established in over 60,000 patients worldwide. All endothelin receptor antagonists have black box warnings for potential liver injury and pregnancy. Glyburide and cyclosporine are contraindicated when used in combination with Tracleer®. He requested Tracleer® be considered for PDL inclusion.

Patricia (inaudible), Gilead, spoke in support of Letairis®. Letairis® is an endothelin receptor antagonist that is selective for the endothelin type-A (ETA) receptor. It is indicated for the treatment of PAH in WHO Group I in patients with WHO class II and III symptoms to improve exercise capacity and delay clinical worsening. The major warnings for Letairis® are the potential risk for liver injury and contraindication to pregnancy. The updated evidenced based treatment algorithm in *Pulmonary Arterial Hypertension*, June 2009, makes a strong recommendation for Letairis® in PAH patients in WHO Functional Class II and III symptoms. She requested consideration of the following scientific advances for inclusion of Letairis® on the PDL: improved exercise tolerance as early as four weeks after initiation of

Letairis®; sustained clinical benefits (95% of patients were alive after 48 weeks of Letairis® therapy [94% were on monotherapy at one year]; 88% of patients were alive at two years with a six minute walk distance improvement sustained over the two year period [82% were sustained on monotherapy]). Letairis® is dosed once per day and the only oral PAH agent available in two doses that has shown efficacy and a consistent dose response. It has no clinically significant drug interactions. She cited the Ambrisentan 222 Phase II open-label single arm study. Because of the risk for liver injury and birth defects, Letairis® is only available through a restricted distribution program called LEAP.

Drug Class Review Presentation – Magellan Medicaid Administration

Dr. Townsend stated that the PAH oral agents is a proposed new PDL class. There are two PDE-5 inhibitors, sildenafil (Revatio®) and tadalafil (Adcirca®) and two endothelial 1 receptor antagonists, ambrisentan (Letairis®) and bosentan (Tracleer®). Sildenafil and tadalafil are indicated to improve exercise ability in patients with PAH. Both delay the time to clinical worsening which is defined variously as a composite of death, transplantation, hospitalization for PAH, initiation of new therapy or worsening functional class. Sildenafil has an additional indication to delay clinical worsening in patients with PAH when used in combination with background IV epoprostenol (Flolan®). Tadalafil was shown to delay the time to clinical worsening of PAH in one pivotal trial that used FDA approved dosing and approximately 50% of the patients were on background bosentan (Tracleer®). There are no head-to-head trials comparing the two PDE-5 inhibitors for PAH. Both show similar improvements in six minute walking distance. The product labeling for both agents is similar with regard to contraindications, precautions and warnings. There are no head-to-head studies comparing the two ET receptor antagonists ambrisentan and bosentan. Both are indicated to improve exercise capacity and delay clinical worsening. Both drugs have black box warnings for serious liver injury and teratogenesis and are only available via a restricted distribution system. It is the recommendation of DHCFP and Magellan Medicaid Administration that the oral drugs for PAH be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Populations

MOTION: Judy Britt motioned that the oral agents for PAH be considered therapeutic alternatives.

SECOND: Michael Hautekeet

VOTES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that it is the recommendation of DHCFP and Magellan Medicaid Administration that both PDE-5 inhibitors (sildenafil and tadalafil) and both ET receptor antagonists (ambrisentan and bosentan) be included on the PDL.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Joseph Adashek motioned to accept Magellan's recommendation to add sildenafil, tadalafil, ambrisentan and bosentan to the PDL.

SECOND: Shamim Nagy

VOTES: Unanimous

MOTION CARRIED

D. Pulmonary Hypertension: Inhaled Prostacycline Analogues

Public Comment

No comment.

Drug Class Review Presentation – Magellan Medicaid Administration

Dr. Townsend stated that the PAH inhaled agents is a proposed new PDL class. There are two inhaled synthetic prostacyclin analogues to be considered, iloprost (Ventavis®) and treprostinil (Tyvaso®). Iloprost has been available in the US since 2004 and is indicated for WHO Group I patients with New York Heart Association (NYHA) Class II through IV symptoms. In controlled trials, it improved a composite endpoint consisting of exercise tolerance, symptoms based on NYHA class and lack of deterioration. Treprostinil was approved in July 2009 for WHO Group I patients with NYHA Class III symptoms to increase walking distance. The efficacy of treprostinil was evaluated in patients on monotherapy with an ET receptor antagonist (bosentan) or PDE-5 inhibitor (sildenafil) and was shown to improve peak six minute walking distance by a placebo controlled median change from baseline of twenty meters after twelve weeks of therapy. There was no significant improvement in time to clinical worsening, NYHA functional class or Borg dyspnea score. An observational finding was a lack of significant improvement in the six minute walking distance in 30% of the patients on background sildenafil. In a pivotal placebo-controlled trial with iloprost as monotherapy, there was improved exercise tolerance, symptoms and lack of deterioration. Iloprost in combination with bosentan was evaluated in two small studies. One study showed a trend of improvement in six minute walking distance and statistically significant improvements in clinical worsening and functional class. The other study was stopped early due to low likelihood of detecting improvement. There are no head-to-head studies for either drug. Both must be administered using specific delivery devices. Iloprost is given six to nine times per day not more frequently than every two hours while awake based on the patient's need and tolerability. Treprostinil has a longer half-life and is dosed during waking hours in four separate sessions approximately four hours apart. The effects of both drugs diminish over the dosing interval and treatment timing can be adjusted for planned activities. There are currently no claims for either drug. It is the recommendation of DHCFP and Magellan Medicaid Administration that the inhalational prostacycline analogues for PAH be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Populations

MOTION: Shamim Nagy motioned that the two the inhalational prostacycline analogues for PAH be considered therapeutic alternatives.
SECOND: Constance Kalinowski
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that is it the recommendation of DHCFP and Magellan Medicaid Administration that iloprost (Ventavis®) be the preferred agent on the PDL.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Joseph Adashek motioned to accept Magellan's recommendation to add iloprost (Ventavis®) to the PDL.
SECOND: Shamim Nagy
VOTES: Unanimous
MOTION CARRIED

E. Fibromyalgia Agents

Public Comment

Jolan Rosenthal, Forest, spoke in support of milnacipran (Savella®). Savella® is a serotonin and norepinephrine reuptake inhibitor. Peer-reviewed publications and a recent meta-analysis have shown SSRIs and TCAs have limited clinical benefit in Fibromyalgia while newer, more specific SNRIs show increased clinical efficacy. Savella® is reported to inhibit

norepinephrine reuptake with an approximate three-fold higher potency over serotonin and does not significantly inhibit other receptors or ion channels. Savella® has a high oral bioavailability of 85%; demonstrates a half-life of approximately 8-10 hours and exhibits linear pharmacokinetics. Absorption is not altered by food; has 13% protein binding and is primarily excreted through the kidneys. There are two pivotal six month and three month trials with a combined total of over 2,000 patients that compared 100mg and 200mg per day with placebo in a double-blind study. Results showed that 100mg and 200mg doses were statistically significantly superior to placebo with approximately one-third of 1,400 Savella® patients meeting rigorous composite responder criteria for up to six months. Savella® has recently demonstrated durability of effect in a six month extension study providing efficacy and safety data for up to one year. Savella® is safe, well tolerated and weight neutral. In both studies, approximately 25% of the patients on Savella® versus 12% on placebo prematurely discontinued due to adverse reactions with the most common being nausea, palpitations and headache. Savella® has a black box warning for suicidality and serotonin syndrome. The recommended dose is 100mg per day and may be increased to 200mg per day based on patient response.

Dr. Adashek asked if there are any studies comparing Savella® to the other drugs within the same class. Ms. Rosenthal replied that there are no head-to-head studies comparing Savella® with any other SNRIs. There is currently an ongoing study which looks at patients who are non-responders on duloxetine having switched to milnacipran.

Dr. Nagy asked if the FDA has approved Savella® for depression. Ms. Rosenthal replied that Forest, at this time, is not looking for the indication of depression in the U.S.

Ken Grant, MD, stated that he teaches at Touro University, and is a practicing rheumatologist with a fair amount of experience with Fibromyalgia patients both Medicaid and non-Medicaid. Patients with pain usually see their primary care physician and studies have shown that many times, they will go from physician to physician and not get adequate treatment for Fibromyalgia and often will go five years or longer without being treated. Patients tend to get frustrated and depressed. Giving primary care physicians options to deal with Fibromyalgia would be reasonably important. Treatment for this is a difficult area to talk about since there are many different causes of it. Patients are often frustrated, hurting and depressed. There are two major ways to think of medication in terms of Fibromyalgia. One is the sensation pain that enters the spinal cord and goes to the central nervous system. One group of drugs, typified by Lyrica®, affects that pathway. The second is the modulation of pain once it is sensed, which is a descending pathway to try and block the pain, typified by the drugs Cymbalta® and Savella®. Many patients often fail the generic version of these drugs. There is no way to be able to discriminate which patient will do well on one drug versus another. There are three FDA indicated drugs for the treatment of Fibromyalgia all with different side effect profiles and mechanisms of action and he requested access be available for all three drugs.

Roy Palmer, Pfizer, spoke in support of Lyrica®. Lyrica® was the first agent to be approved for Fibromyalgia based upon five studies of 4,000 patients up to six months. The efficacy, safety and adverse event profiles are well characterized. Lyrica® binds with alpha2-delta, a subunit of voltage-gated calcium channels, which has efficacy on the ascending pathway and some efficacy on the descending pathway. It's good to have different mechanisms of action so an SNRI can be switched to an alpha2-delta which provides a different approach to treating patients. Lyrica® is renally cleared and has little potential for drug-drug interactions. In 2009, prior authorization criteria were put in place restricting Lyrica® to the FDA-approved indications. Utilization decreased by half indicating appropriate use of the drug and his company supports continuation of the PA criteria. He requested that the Committee consider drugs with different mechanisms of action be available to offer options for patient and prescribers.

John Brokars, Lilly, spoke in support of Cymbalta®. SNRIs carry a class black box warning for increased suicidality in patients with major depressive disorder (MDD) in children and adolescents and should not be used in combination with MAOIs. Hepatic failure, sometimes fatal, has been reported with Cymbalta® and patients taking NSAIDs, aspirin or blood thinners may have an increased bleed risk. Cymbalta® is a once daily, non-controlled

selective serotonin and norepinephrine reuptake inhibitor with a unique one to one ratio of norepinephrine and serotonin. It's indicated for MDD, generalized anxiety disorder (GAD), Diabetic Peripheral Neuropathic Pain, Fibromyalgia and a new indication for musculoskeletal pain. 73% of Fibromyalgia patients will experience major mood disorder in their lifetime, 62% will experience MDD and 55% will have anxiety disorder. Cymbalta® demonstrated 60mg once daily in two randomized double-blind control trials for Fibromyalgia involving patients with and without MDD. Both trials showed pain and reaction results which were statistically significant at the end of the trial in both types of patients. In two clinical trials, 51% and 55% of the patients taking Cymbalta® once daily had clinically meaningful pain relief as measured by 30% improvement. Fibromyalgia guidelines recommend Cymbalta® be used for patients who have prominent symptoms of sleep disturbance, chronic fatigue, depression and widespread pain. Cymbalta® has been recommended in Fibromyalgia treatment guidelines since 2005. Cymbalta® has a consistent safety profile and has demonstrated early and significant improvement in pain in patients with and without MDD. Nevada Medicaid restricts use of Cymbalta® to the ICD-9 code 729.1 which has significantly reduced usage. He requested Cymbalta® remain on the PDL for appropriate use in patients with Fibromyalgia.

Christine Page, Fibromyalgia patient, stated that she has had fibromyalgia most of her life, has seen many disbelieving physicians and was not diagnosed until the age of 35 (she is currently 56). She has taken a multitude of unsuccessful medications which lead to multiple adverse drug reactions with no relief of pain and resulted in hospitalization for seizures. This intolerance of medications is common among people with Fibromyalgia. She was placed on Cymbalta® which provided relief without the side effects. She requested that the Committee consider the additional suffering patients endure while failing one unsuccessful treatment after another. The practice will lead to more members of society becoming disabled and increase the State's societal responsibility for their long term care. She stated that she was a registered nurse for thirty years and no longer able to work due to the severity of her illness. She felt that if the drugs being considered today were given to her early in her illness, she would still be working. Ms. Page did not feel that a "fail first" policy could be cost effective or promote positive patient outcomes.

Dr. Manthei stated that written comment was provided by Dr. Edmund Pasimio (copies were distributed to the Committee prior to the start of the meeting).

Drug Class Review Presentation – Magellan Medicaid Administration

Dr Townsend stated that the Fibromyalgia agents are a proposed new PDL class. The three drugs with FDA approval for the treatment of Fibromyalgia are duloxetine (Cymbalta®), milnacipran (Savella®) and pregabalin (Lyrica®). Both Cymbalta® and Lyrica® have other indications. Savella® is only indicated for Fibromyalgia. All three agents currently have DUR Board criteria applied allowing coverage for an ICD-9 of Fibromyalgia. There is no head-to-head data and studies have been conducted in differing populations with different outcome measures in each respective pivotal trial. There is insufficient evidence to allow for a clinically sound comparison of efficacy among the agents or between one of these FDA-approved products and those that are used off-label for Fibromyalgia. A clinical choice may be made based on the individual patient symptoms to be targeted or the adverse drug interaction profiles of the various agents. The claims database for the past three months (not ICD-9 specific) reflects use of Cymbalta® for all of its indications for 501 recipients, Lyrica® for all of its indications, 315 recipients and Savella® for its only indication of Fibromyalgia, 63 recipients. It is the recommendation of DHCFP and Magellan Medicaid Administration that the three drugs FDA approved for Fibromyalgia be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Populations

Dr. Adashek asked if there is no head-to-head data, how it can be determined that they are therapeutic alternatives. Dr. Townsend replied that the outcome parameters used in the trials don't allow for a good fair comparison among them. They are FDA approved and demonstrated some efficacy in the treatment of Fibromyalgia.

Dr. Nagy asked if a PA will be required for these agents and if additional medications are needed; i.e., antidepressants, is another diagnosis needed. Dr. Townsend stated that the DUR Board has applied clinical criteria for use of these drugs. If an ICD-9 consistent with Fibromyalgia (729.1) is included on the prescription by the prescriber and transmitted through the pharmacy system, the claim will adjudicate. The prescriber can also contact the Clinical Call Center with the diagnosis of Fibromyalgia and the claim will adjudicate. Lyrica® and Cymbalta® have other indications which are also controlled by an ICD-9 approved by the DUR Board.

MOTION: Weldon Havins motioned that the three agents in this class be considered therapeutic alternatives.
SECOND: Shamim Nagy
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that it is the recommendation of DHCFP and Magellan Medicaid Administration that all three drugs be included on the PDL.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Joseph Adashek motioned to add the three agents, Cymbalta®, Savella® and Lyrica® to the PDL.
SECOND: Weldon Havins
VOTES: Unanimous
MOTION CARRIED

IV. Established Drug Class Reviews

A. Sedative Hypnotics

Public Comment

No comment.

Drug Class Review Presentation – Magellan Medicaid Administration

Dr. Townsend stated that this is an existing drug class on the PDL and is being reviewed due to a new drug approved, doxepin (Silenor®) 3mg and 6mg tablets. Doxepin is a sedating tricyclic antidepressant. Silenor® is indicated for the treatment of insomnia characterized by difficulty in sleep maintenance. The usual dose is 6mg taken thirty minutes before bedtime. Silenor® has been compared to placebo in patients with chronic primary insomnia where it improved sleep parameters. The American Academy of Sleep Medicine's position is that first line treatment is a benzodiazepine receptor agonist modulator or Rozerem®. Those that fail should try a different drug in these classes. Those unsuccessfully treated may benefit from a sedating low-dose antidepressant such as trazadone, mirtazapine, doxepin, amitriptyline or trimipramine. The opinion of the Academy is that no one of these third-line products is preferred over the others. Currently on the PDL are estazolam, flurazepam, Rozerem®, temazepam, triazolam and zolpidem. Trazadone is on the PDL as an antidepressant and the older antidepressants; e.g., amitriptyline, are also available. Tricyclics are not a managed drug class and are openly available. It is the recommendation of DHCFP and Magellan Medicaid Administration that the sedative hypnotic agents be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Populations

MOTION: Joseph Adashek motioned that the sedative hypnotic agents be considered therapeutic alternatives.

SECOND: Weldon Havins
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by Magellan Medicaid Administration and the Division of Health Care Financing and Policy

Dr. Townsend stated that it is the recommendation of DHCFP and Magellan Medicaid Administration that no changes be made to the Sedative Hypnotic class on the PDL.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Michael Hautekeet motioned to accept Magellan's recommendation that no changes be made to the Sedative Hypnotic class on the PDL.
SECOND: Joseph Adashek
VOTES: Unanimous
MOTION CARRIED

V. Report by Magellan Medicaid Administration on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Dr. Townsend presented the report for Committee review. In response to Dr. Havins question, Dr. Townsend stated that the new drugs or dosage forms included in the report will be reviewed at the March 2011 and June 2011 meetings.

VI. Review of Next Meeting Location, Date, and Time

The next meeting is scheduled for March 24, 2011, at the Las Vegas Chamber of Commerce with videoconferencing to the Magellan Medicaid Administration office in Reno.

Dr. Manthei asked how the removal of Darvocet® and Darvon® from the market is being addressed. Dr. Townsend stated that these drugs are not on the PDL and have been coded in the system to disallow coverage based on the FDA withdrawal.

VII. Public Comment

No comment.

VIII. Adjournment

MOTION: Joseph Adashek motioned to adjourn the meeting.
SECOND: Weldon Havins
VOTES: Unanimous
MOTION CARRIED
The meeting was adjourned at 2:23 p.m.